purchasers for resale have not already received such notice pursuant to Part VI E). Part X B requires proposed respondents to institute a purchaser for resale order compliance surveillance program and Part X C states that proposed respondents must terminate sales to those purchasers for resale they know or should know are violating Parts I through V of the proposed order. Part XI would allow proposed respondents to make any representation for any drug that is permitted by the FDA in the drug's labeling, and would allow proposed respondents to make any representation that is specifically permitted in the labeling for any product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

Part XII of the proposed order contains record keeping requirements for materials that substantiate, qualify or contradict claims covered by the proposed order. Part XIII of the proposed order requires distribution of a copy of the order to current and future officers, employees, and agents. Part XIV provides for Commission notification upon a change in the proposed corporate respondent and Part XV requires Commission notification when the proposed individual respondent changes his business or employment. Part XVI requires the proposed respondents to file with the Commission a report demonstrating compliance with the terms and provisions of the order. Part XVII provides for the termination of the order after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate the public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and the proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 01–15546 Filed 6–19–01; 8:45am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01106]

Addressing Asthma From a Public Health Perspective; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program for ''Addressing Asthma from a Public Health Perspective.'' This program addresses the ''Healthy People 2010'' focus areas Environmental Health, Respiratory Diseases and Occupational Safety and Health.

The purpose of the program is: Part A: Developing State Capacity to Address Asthma and Part B: Implementation of State Asthma Plans.

This funding is not to be used for any type of research.

B. Eligible Applicants

Assistance will be provided only to health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments.

In consultation with States, and with the written concurrence of the State, assistance may be provided to political subdivisions of States.

Part A: Eligible applicants are those entities listed above that do not have a finalized comprehensive asthma plan or a well developed asthma surveillance system. Grantees currently funded by CDC Announcement #99109 (Attachment 1) are not eligible to apply.

Part B: Eligible applicants are those entities listed above that have a completed comprehensive asthma plan and have an operational surveillance system for asthma. Grantees currently funded by CDC Announcement #99109 are eligible to apply. However, if awarded funds under Part B of this announcement, applicant will lose funds under Announcement #99109.

An eligible applicant may apply for both Part A and Part B; however, only one award per applicant will be made. To apply for both parts of this announcement, applicants must submit separate applications for Part A and Part B.

Note: Title 2 of the United States Code, Chapter 26, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately $3,600,000 is available in FY 2001 to fund awards under this announcement. Funding estimates may change.

Part A: Developing State Capacity to Address Asthma. Approximately $2,000,000 is available to fund approximately 7–12 awards. It is expected that the average award will be $200,000. Additionally, $100,000 is available to increase Part A awards up to $10,000 each, if an occupational component is included in the application and is favorably reviewed.

Part B: Implementation of State Asthma Plans. Approximately $1,500,000 is available to fund approximately 2–4 awards. It is expected that the average award will be $700,000.

It is expected that the awards will begin on or about September 30, 2001 and will be made for a 12-month budget period within a project period of up to 3 years for Part A and 5 years for Part B.

Continuation awards within the approved project periods will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Applicant should document assurance of ability of project staff to travel to Atlanta to participate in the CDC National Asthma Conference and/or grantee meetings and willingness to share innovations, information, data and materials.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

Part A. Developing State Capacity to Address Asthma

1. Recipient Activities:

a. Develop or finalize a comprehensive State asthma plan.

b. Develop and organize collaborative linkages with appropriate agencies and organizations.

c. Implement a new (or enhance an existing) asthma surveillance system.

d. Begin the statewide intervention program upon completion of the plan.

e. Evaluate all activities ongoing and document lessons learned at the end of the project.

Part B. Implementation of State Asthma Plans

a. Maintain existing statewide coalition and partnership activities to oversee implementation and evaluation of the plan. Expand partnership activities as appropriate.

b. Maintain existing asthma-related activities currently underway in the health agency and expand as appropriate.

c. Implement defined aspects of the completed State/territorial/tribal asthma plan. Assure institutionalization of intervention activities.

d. Expand and continue existing surveillance efforts related to asthma occurrence, severity, management and other indicators in order to monitor the effectiveness of the intervention activities.

e. Evaluate each intervention activity and the program as a whole; document lessons learned.

2. CDC Activities for Parts A and B

a. Collaborate with the recipient in all stages of the project and coordinate joint activities among all grantees.

b. Provide programmatic technical assistance, as requested.

c . Convene meetings for grantees to share experiences, data, and materials.

E. Content

Letter of Intent (LOI)

A one-page, non-binding LOI is requested, and it should include:

1. Name and address of organization
2. Contact person
3. Which part of the announcement, Part A, Part B or both, applied for.

The LOI will be used to ascertain the level of interest in this announcement and to assist in determining the size and composition of the independent review panel.

Applications

Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 30 pages for Part A, or 40 pages for Part B, double-spaced, printed on one side, with one inch margins, and unreduced font. The application must be submitted unstapled and unbound.

Part A: Developing State Capacity to Address Asthma. Include each of the following sections:

1. Description of Problem

Describe what is known of the asthma problem in the State or jurisdiction and efforts, to date, to begin to systematically address the problem. Describe the barriers that need to be addressed in the development of a comprehensive asthma program in the State. Describe how the agency as a whole will focus its efforts on asthma. If the applicant seeks funds for the occupational asthma component, describe the plan and justify its need.

2. Collaborative Relationships

Describe experiences with collaborative relationships around asthma or with other chronic or environmentally related or work-related disease problems requiring extensive collaborative relationships both within and outside the agency.

Specifically define the approach to be used to establish or further develop these relationships. Documentation of partnerships with the clinical community is essential, including the applicant's plan for working with local health agencies, physician organizations and community health centers. In addition, applicants should document their plan to work with their State chapter of the American Lung Association, local education authorities, and groups or organizations that serve minority or other populations experiencing a disproportionate burden of asthma. If one or more of these partners will not be included, the applicant should explain why.

Letters of commitment from specific organizations, including a statement of their intention to collaborate, will considerably strengthen the application. Note that grant funds should be used to leverage asthma program development in the State/territory/tribe along with resources from other collaborative agencies and organizations.

3. Planning and Evaluating Processes

For those States/territories/tribes without an existing asthma plan, describe the process by which the plan will be developed. Include information about the agencies and organizations that will be included in the planning process. Include a description about how the collaborative relationship will be used when the agency has a plan in place and is ready to implement interventions. The plan must address all persons with asthma in the State regardless of age, race/ethnicity or gender. Include a discussion of the place of occupational and work-related asthma in the plan if funds are requested for that component.

If a State asthma plan already exists, describe the portion of the plan to be implemented with these grant funds.

Provide specific objectives for the proposed activities that are realistic, time-phased, and measurable and reflect the three-year period of this announcement. Describe how progress made toward meeting objectives will be evaluated and documented.

4. Surveillance System

The applicant should include a surveillance system plan containing: (a) A description of data currently available to the program; (b) the data the agency will obtain; (c) plans for identifying at-risk populations (e.g., ethnic groups, socio-economic groups, and/or geographic areas); (d) how the agency will use this data to develop ongoing surveillance; and (e) how the surveillance data will be used to support policy development, program planning and evaluation activities.

Participants funded under this announcement will be expected to use the Behavioral Risk Factor Surveillance System (BRFSS) supplemental asthma module at the first available opportunity, preferably within the first year of the project.

5. Management and Staffing Plan

Describe the qualifications and roles of the trained public health professionals to serve as: an asthma coordinator for the agency's program and to manage the planning process and conduct other programmatic activities; an epidemiologist, at least 0.5 FTE, to develop and implement surveillance activities for the asthma project; and a supervisor who will assure support for the project staff. Other support positions may also be proposed.

Include a plan to expedite filling of the staff position(s) and assure that they have been or will be approved by the applicant's personnel system. Where current staff already fill these roles and federal resources are not to be used for their support, information on the position and qualification of the person filling the position should be provided.

Describe the organizational location of the proposed staff, their relation to the State's ''asthma contact'' (the position in the agency currently responsible for contact with CDC on asthma issues), and the support within the organizational structure for the activities defined for the project staff. Include an organizational chart for the unit in which the activity will be located and, at a minimum, the next two levels above it.

For each position describe the primary roles and responsibilities for the project staff over the three-year grant period. Also, include the specific staff

activities that will contribute to meeting each objective.

6. Budget

This section must include a detailed first-year budget and narrative justification and future annual projections. The applicant should describe the program purpose for each budget item. For contracts contained within the application budget, applicants should name the contractor, if known; describe the services to be performed; justify the use of a third party; and provide a breakdown or a justification for the estimated costs of the contracts, the kinds of organizations or parties to be selected, the period of performance, and the method of selection. The budget should include travel for project staff to meet once per year with CDC and other grantees. Any requested funds for an occupational component must be presented separately, with the same level of detail, immediately following the main budget narrative justification.

Part B: Implementation of State Asthma Plans

Include each of the following sections:

1. Description of Problem

Describe what is known of the asthma problem in the State or jurisdiction. Include a description of populations at increased risk of poorly controlled asthma within the jurisdiction (e.g., ethnic groups, socio-economic groups, geographic areas). Attach published surveillance reports that describe asthma within the jurisdiction including a report on asthma in the Medicaid population.

2. Asthma Plan

Provide the existing asthma plan as an attachment. Describe how the asthma plan and the plan's implementation strategy were developed, including a list of the partners participating in the process (if not part of the published plan) and support for the final plan as demonstrated by a letter from the Agency's Health or Medical Director and from key partners (e.g., the Director of the State/territorial American Lung Association and key professional societies). Attach a copy of the final plan. The final plan (or attachments to that plan) must include: (a) an assessment of the asthma burden in the State/tribe/territory using population-based data; (b) measurable objectives that address people with asthma across the State/territory/tribe and include people with asthma of all ages, race/ethnic groups, and gender; (c) a description of how the plan's implementation would reach all persons with asthma in the State regardless of age, race/ethnicity, or gender, (d) proposed strategies to meet the plan's objectives, including, but not limited to, efforts to (d.1) expand surveillance for asthma, (d.2) improve provider compliance with the National Asthma Education and Prevention Program's ''Guidelines on the Diagnosis and Management of Asthma,'' (Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health, National Heart, Lung, and Blood Institute. NIH Publication No. 97–4051, April 1997), (d.3) improve the skills of patients and families affected by asthma to manage the disease, and (d.4) evaluate the program's implementation and measure progress toward objectives; and (e) an assessment of existing and needed resources to implement these strategies.

3. Partnership Oversight

Describe how the partners who developed the asthma plan will continue to implement and monitor the intervention activity and modify the plan over time.

4. Surveillance and Evaluation

Describe the surveillance system currently in place within the health agency and its ability to support the evaluation of intervention activities and a continued planning process. All asthma indicators assessed over time should be noted (including, but not limited to, prevalence, mortality, hospitalization, emergency care and measures of disease management status), and a copy of all asthma surveillance reports, brochures, or publications should be provided. If available, analyses of Medicaid data on persons with asthma should be provided. Ability to provide measurement of progress in meeting all plan objectives should be addressed. Intentions to use BRFSS asthma module(s) and the frequency of use should be included; also, plans for further development of the asthma surveillance activity should be presented in detail. Surveillance of occupational asthma is encouraged and must be discussed.

5. Implementation of the Asthma Plan

a. Identify the specific objectives of the asthma plan that are to be focused upon and the specific intervention strategies from the plan to be implemented that will use the resources provided through this announcement. Interventions that change systems and individuals to provide improved disease management or education are preferred. Provide specific realistic, measurable, and time-phased process objectives for each of the strategies and interventions to be implemented that reflect the five year period of this announcement. Describe how both process and outcome objectives for all activities will be evaluated and documented.

b. Demonstrate the scientific basis for proposed interventions. If proposed interventions include case management programs, assure that patients enrolled are those with moderate to severe persistent asthma and are receiving care consistent with the National Asthma Education and Prevention Program (NAEPP) Clinical Practice Guidelines (Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health, National Heart, Lung, and Blood Institute. NIH Publication No. 97–4051, April 1997). Explain how it was decided by members of the statewide partnership group that these particular objectives and strategies will be addressed.

c. Describe what objectives and strategies from the plan are currently being addressed utilizing other resources.

d. Demonstrate that the plan addresses asthma in persons of all ages, race/ethnic groups, and gender and includes key environments in which persons with asthma spend significant time (e.g., home, school, workplace). Include a discussion on the place of occupational asthma in the plan.

e. Explain how the resources from this solicitation will be utilized to leverage additional resources for implementation of other components of the plan. Explain how interventions will be institutionalized and sustained without these funds.

6. Management and Staffing for Intervention Activities

a. Describe existing asthma program staff within the health department and their management structure, the current function of the asthma staff, and their role in this project plan. If plan implementation will be coordinated from an office other than within the health department, describe that office and its staff, the oversight of that office and its staff, and the ties of that office to the health agency. Provide an organizational chart for the health agency that identifies the unit(s) in and out of the health agency that will participate in the proposed activities.

b. Describe asthma surveillance staff and their role within the project activities. Describe all staff who will be responsible for oversight of program evaluation.

c. If intervention activities will be implemented through contracts, define the process by which these contracts will be awarded and monitored.

d. Describe staff available or to be hired for those aspects of the plan to be implemented with these resources. For each position, describe the primary roles and responsibilities over the five-year grant period.

e. Include the specific staff activities that will contribute to meeting each objective that is to be addressed. Discuss the role of the statewide partnership group in oversight of intervention activities

f. Document assurance of ability of key project staff to travel to Atlanta to participate in the CDC National Asthma Conference and/or grantee meetings and willingness to share innovations, information, data and materials.

7. Budget

This section must include a detailed first-year budget and narrative justification and future annual projections. The applicant should describe the program purpose for each budget item. For contracts contained within the application budget, applicants should name the contractor, if known; describe the services to be performed; justify the use of a third party; and provide a breakdown or a justification for the estimated costs of the contracts, the kinds of organizations or parties to be selected, the period of performance, and the method of selection. The budget should include travel for key project staff to meet once per year with CDC and other grantees. This section should also include a listing of other funds, outside the cooperative agreement, that will be used to support this intervention.

F. Submission and Deadline

Letter of Intent (LOI)

On or before July 19, 2001, submit the LOI to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Submit the original and two copies of PHS 5161–1 (OMB Number 0920–0428). Forms are available in the application kit at the following Internet address: www.cdc.gov/od/pgo/forminfo.htm.

On or before August 17, 2001, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date; or

2. Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late: Applications which do not meet the criteria in 1. or 2. above will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

Part A: Developing State Capacity to Address Asthma

1. Description of the problem (10 points)

The extent to which the agency's commitment to addressing asthma is demonstrated by accomplishments to date in understanding the problem.

2. Collaborative Relationships (20 points)

The demonstration and description of prior successful collaborations to address asthma or other chronic or environmentally related or occupationally-related problems. The appropriateness of organizations and agencies identified. The level of commitment of key organizations as demonstrated by the content of the letters of commitment.

3. Planning and Evaluating Processes (35 points)

For those applicants without an existing asthma plan, the appropriateness of the planning and implementation process proposed. The extent to which objectives are consistent with the stated purpose of the announcement are measurable, time-phased and the ability of the applicant to meet the objectives according to the specified time table. The adequacy of the applicant's plan to monitor progress toward meeting the stated objectives.

4. Surveillance System Plan (15 points)

The extent to which the description of the surveillance system includes all elements outlined in the application content section and the quality and extent of submitted surveillance reports.

5. Management and Staffing Plan (20 points)

The extent to which the role of proposed staff is defined and the agency has identified adequate qualifications of and level of commitment for the proposed staff; and the level of organizational support available to the project staff.

6. Budget (not scored)

The extent to which the budget is reasonable, adequately justified and consistent with the intended use of the cooperative agreement funds.

Part B: Implementation of State Asthma Plans

1. Description of the Problem (5 points)

The extent to which the agency's commitment to addressing asthma is demonstrated by accomplishments to date in understanding the problem. The extent to which the agency has been able to identify populations at increased risk and effectively disseminate and use that information in the planning process.

2. Asthma Plan (20 points)

The extent to which a wide variety of appropriate partners were engaged to develop the plan; the commitment by the Agency to the implementation of this plan as demonstrated by the inclusion of a letter of support from the Secretary of Health or the Agency's Medical Director; the extent to which the intervention plan is supported in the community by the inclusion of letters of support from key members of the community; the extent to which the asthma plan is comprehensive and includes the items listed in the application section for this announcement.

3. Partnership Oversight (10 points)

The extent to which appropriate partners will be a part of the implementation and oversight of the implementation.

4. Surveillance and Evaluation (20 points)

The current state of the surveillance system; the quality of surveillance reports provided; the ability to provide measurement of progress in meeting all plan objectives; the plan for appropriate continued development of the asthma surveillance activity. The ability to support evaluation of implementation activities.

5. Implementation of the Asthma Plan (30 points)

Clear link between the plan and the proposed implementation; the appropriateness and scientific support for the proposed implementation; the involvement of statewide partners in development of the proposed

implementation and its monitoring over time; the use of these resources to leverage additional resources for plan implementation; the plans to institutionalize specific interventions; specific objectives that are realistic, measurable and time phased; clear definition of both process and outcome measures for the evaluation of implementation activities.

6. Management and Staffing for Intervention Activities (15 points)

The current functioning of asthma staff (program and surveillance) within the health agency; the description of staff to be hired or contracts to be developed; the link of staff to program objectives; the continued role of the statewide partnership group. Assurance that key personnel will attend scheduled grantee meetings and CDC-sponsored national asthma conferences, and that the applicant agrees to share innovations, information, data and materials.

7. Budget (Not scored)

The extent to which the budget is reasonable, adequately justified and consistent with the intended use of the cooperative agreement funds.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Annual progress reports;
2. financial status report, no more than 90 days after the end of the budget period; and
3. final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 2 of the announcement in the application kit.

AR–7 Executive Order 12372 Review
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317 of the Public Health Service Act, [42 U.S.C. section 241 and 247b], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where to Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address http://www.cdc.gov Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To obtain business management technical assistance, contact: Sonia Rowell, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: (770) 488–2724, Email address: svp1@cdc.gov.

For program technical assistance, contact: Leslie P. Boss, Air Pollution and Respiratory Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, Mailstop E–17, 1600 Clifton Rd., NE, Atlanta, GA 30333, Telephone number: (404) 498–1002, Email address: LBoss@cdc.gov.

Dated: June 14, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–15476 Filed 6–19–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0051]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Adverse Event Pilot Program for Medical Devices and Blood Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written or electronic comments on the collection of information by July 20, 2001.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Adverse Event Pilot Program for Medical Devices and Blood Products

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device related deaths, serious injuries, and malfunctions and to require user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 213 of the FDA Modernization Act of 1997 (FDAMA) amended section 519(b) of the act relating to mandatory reporting by user facilities of deaths and serious injuries and serious illnesses associated with the use of medical devices. This amendment required FDA to, by regulation, replace universal user-facility reporting with a system that is limited to a '' * * * subset of user facilities that constitutes a representative profile of user reports'' for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the act.

FDA is the Federal agency charged with the responsibility for ensuring that marketed medical products are safe and effective. To carry out its responsibilities, the agency needs to be informed whenever an adverse event or product problem occurs. Only if FDA is provided with such information will it be able to evaluate the risk, if any, associated with the product and take whatever action is necessary to reduce or eliminate the public's exposure to this risk. Data collected from user facilities about problems with medical devices assist FDA to carry out that mission as it pertains to medical devices. Prior to implementing the regulation to change from universal user-facility reporting to reporting by a subset of user facilities, FDA is planning to conduct a pilot program to evaluate various aspects of the new program. The new user-facility program that will be